



DEPARTMENT OF HEALTH AND HUMAN SERVICES

148126

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

September 5, 2003

WARNING LETTER

CIN-03-18969

Sent by Federal Express

Dennis Dirksen
591 Cassella Montezuma Road
Maria Stein, OH 45860

Dear Mr. Dirksen:

An investigation at your dairy operation conducted by an investigator from the Food & Drug Administration (FDA) and an investigator from the Ohio Department of Agriculture on June 04, 2003 confirmed that you offered an animal for sale for slaughter for food in violation of the Federal Food, Drug, and Cosmetic Act (the Act). The animal was adulterated food within the meaning of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Act

On or about March 07, 2003, you sold a cow, identified with backtag # 31ZY8952 and USDA/FSIS retain tag # 46272000, for slaughter as human food at [REDACTED]. The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) analysis of the kidney, liver and muscle tissues from that animal disclosed the presence of violative Penicillin residue levels of 0.57 ppm, 0.07 ppm, and 0.07 ppm, respectively. The established tolerance for this drug in cattle intended for slaughter as human food is 0.05 ppm (Title 21, Code of Federal Regulations, Section 556.510). The presence of this drug at the reported levels in this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act

Our investigation also found that you hold animals under conditions whereby medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack adequate systems for assuring: (1) that drugs are used in a manner not contrary to the directions contained in the labeling; and (2) that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. The investigators found that you have no animal medication records that would identify which animal had been medicated, what type of medication had been used, and what the withdrawal time should be. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act

You are also adulterating within the meaning of Section 501(a)(5) the veterinary drug Agri-cillin (penicillin) that your firm uses on cows when you fail to use it either in conformance with its approved labeling or, if used in an extra-label manner, in accordance with a lawful order of a licensed veterinarian and in compliance with the extra-label use regulations at 21 CFR Part 530. You did not have a veterinarian's order for use of Agri-cillin in the manner you used it, i.e. with

an inadequate withdrawal period. Use of penicillin in a manner for which you did not have a veterinarian's order causes the drug to be unsafe within the meaning of Section 512 of the Act. Additionally, because your use of Agri-cillin resulted in the presence of residue above the accepted tolerance in the edible tissue of cows, your use of this drug was not in compliance with 21 CFR 530.11(d). Your use of penicillin in a manner not in compliance with extra-label use regulations causes the drug to be unsafe within the meaning of Section 512 of the Act.

Lastly, this investigation revealed that you falsely provided a "Drug Residue Free" guarantee to the buyer of this animal, thus causing an animal bearing illegal drug residues to be slaughtered for food. The FD&C Act is a strict liability statute, which requires anyone in a position of responsibility with the authority and power to prevent a violation to exercise all necessary care to prevent the violation. It is important for you to realize that it is a felony criminal offense to intentionally offer false or misleading information which results in a violation of the Act.

It is your responsibility to assure that your operations are in compliance with the law. To avoid future illegal residue violations you should take precautions such as:

- Implementing a system to identify which animals have been medicated and with what drug(s); and
- If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. This action may include, but is not limited to, obtaining a court injunction against directly or indirectly offering livestock for slaughter for food

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to: Deborah Grelle, Director of Compliance, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

For your information, included with this letter are two (2) notices that many auction markets in the state of Ohio have posted in an effort to prevent violations of the Food Drug, and Cosmetic Act. These notices provide information concerning your responsibilities under the Food, Drug, and Cosmetic Act and the circumstances under which you can be held liable for violations to the Act's provisions.

If you have any questions about the contents of this letter, please call Mr. David Radle, Tissue Residue Monitor, at (513) 679-2700 extension 124.

Sincerely,



Carol A. Heppe
District Director

Enclosures